REMARKS/ARGUMENTS

Upon entry of this amendment, Claims 25, 30-36, 39-42, 44-46, 50, 52 and 55 are pending.

Claims 1-24, 26-29, 37-38, 43, 47-49, 51 and 53-54, including claims subject to restriction and non-elected, have been canceled. Claim 25 is amended to replace the reference to claim 50. Claims 32 and 42 are amended to insert "bacterial" after "pathogenic". Claims 34, 44 and 52 are amended to clarify claim language. Claim 50 is amended as discussed below. New claim 55 is provided as another independent claim.

The language of these claims describing the polypeptide is supported specifically at page 19, line 27-page 20, line 9 and page 20, line 24 through page 21, line 4. Specifically, support for the description of an epitope of the OMP85 sequences, and for the polypeptide to have the ability to induce antibodies which interfere with the binding to the known cellular targets of *N. gonorrhoeae* or *N. meningitidis*, *i.e.*, epithelial cells, is found at page 25, lines 25-29.[1] The specification describes the use of such OMP85 antigenic polypeptides as diagnostic reagents at page 29, line 16 to page 30, line 5. The description of an epitope of OMP85, *e.g.*, the exemplary N-terminal sequence used to generate antibodies used in the examples, provides written description for dependent claims, as noted in the preceding response. Other portions of the specification are identified in the preceding response.[2]

The above amendment to the specification corrects the grant numbers and language required to support same.

No new matter is introduced into the specification by these amendments.

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[1] See, also, page 17, line 12: "All *Neisseriae* species colonize mucosal surfaces." It is known to one of skill in the art that mucosal surfaces are formed by epithelial cells.

[2] See, *e.g.*, pg. 20, lines 26-29; pg. 25, lines 25-30; pg. 26, line 14 through pg. 27, line 2; pg. 35, lines 7-10; pg. 52, line 29 through pg. 53, line 7 and Fig. 6, and other support recited in response dated June 12, 2007.

I. 35 USC §112, First Paragraph Rejections – New Matter

(a) Claims 43 and 51 are rejected (a maintained rejection) on this ground for allegedly containing subject matter not described in the specification, i.e., "peptide lacking a signal sequence" because the examiner asserts that identifying the signal sequence in one of the OMP85 sequences of the specification is not sufficient to teach one of skill in the art that the identical sequence used in another OMP85 sequence which is 95% identical to the first sequence is also a signal sequence.

(b) Claim 50 and its dependent claims are newly rejected as allegedly reciting that the antibodies induced by the immunogenic composition comprises an isolated polypeptide comprising an amino acid sequence having 95% or greater sequence identity with the amino acid sequence of SEQ ID NO: 4". The examiner states that the first 178 aa of SEQ ID NO: 2 does not constitute an amino acid sequence having 95% or greater sequence identity with the 797 residues of SEQ ID NO: 4. The examiner states that the insertion of "epithelial" to characterize the term "mammalian cells" in the claims renders the claims broader. The examiner rejects the term "mammalian patient" as excluding the rabbit model in which the antibodies were generated.

Applicants respectfully request reconsideration and withdrawal of these grounds for rejection in view of the following arguments.

Because the examiner is rejecting the claim language, not any language that is being inserted into the specification, the proper rejection is based on lack of written description, ***not*** new matter. See, *e.g.*, MPEP §2163.06. Applicants thus further discuss this rejection as directed to the written description requirement. The standard for determining compliance with the written description requirement, as stated in MPEP §2163.02 and in the case law cited therein, is as follows: An applicant must convey with ***reasonable*** clarity to those ***skilled in the art*** that, as of the filing date sought, he or she was in possession of the invention.

i. Claims 43 and 51

The rejection summarized in (a) is rendered moot by cancellation of claims 43 and 51, which cancellation is submitted to advance prosecution.

ii. Description of "mammal"

Claim 50 has been amended to replace "mammalian patient" with "mammal". Claim 55 uses the same language. This language is supported by the recitation at specification page 26, lines 16-20 and line 27-29; and page 51, Example 7.

iii. Description of "epithelial cells"

The examiner's suggestion that "epithelial cells" are not supported by written description in the specification is not correct. As noted in footnote 2, on page 17, the specification clearly states that all *Neisserial* species colonize mucosal surfaces. One of skill in the art is aware that mucosal surfaces are composed of epithelial cells. *Neisseriae* species are, and were at the time of the priority filing date, known to bind to mammalian *epithelial* cells. This is why the art recognized the use of Chang epithelial cells as appropriate cellular target models to study the binding of *Neisseriae*. See, *e.g.*, De Vries *et al*, **1996** Infec Immun, 64(8):2998-3006; Duensing and Van Putten, **1997** Infec. Immun., 65(3):964-970; and Stephens *et al*, **1982** Infection, 10(3):192-195, among others. All of these documents are provided in the attached supplemental Information Disclosure Statement for ease of review.

iv. Description of the protein/polypeptide that induces antibodies to SEQ ID NO: 4

Claim 50's description of the amino acid sequence of 95% identity to SEQ ID NO: 4 and new claim 55's recitation of an epitope of SEQ ID NO: 4, as both being able to induce antisera are also supported by written description in the specification. Given the description provided, the person of skill in the art would understand that Applicants' were in possession of the essential information of the claims.

The specification provides written description at page 20, lines 25-29 through to page 21, line 4 that the full-length OMP85 or sequences representing an epitope thereof, have the ability to induce antibodies to the cellular targets of *Neisseriae*, *e.g.*, epithelial cells or mucosal cells, such as *exemplified* in Example 8. All of this teaching, which is in the original priority specification, thus provides description sufficient for one of skill in the art to understand that the *N. meningitidis* and *N. gonorrhoeae* OMP85 proteins

contain an epitope sequence that is recognized by the antisera developed to the exemplified *N. gonorrhoeae* OMP85.

Example 8 provides written description of the use of a sequence containing an epitope found within an OMP85 amino acid sequence. In this instance, the OMP85 sequence (SEQ ID NO: 2) has at least 95% sequence similarity to SEQ ID NO: 4. Example 8 discloses the use of antisera developed to a fusion protein of the first 178 AA of SEQ ID NO: 2; the 178AA sequence differs between the two species by 3 amino acids, as shown in Fig. 5. The specification at Example 7 and Fig. 6 provides written description that the same antisera bound to OMP85 proteins of various *N. meningitidis* and *N. gonorhroeae* strains in the Western blot. Clearly, this description conveys to one of skill in the art that antisera to amino acid 1-178 of SEQ ID NO: 2 binds to the OMP85 sequence of SEQ ID NO: 4, and thus that both the *N. gonorrhoeae* and *N. meningitidis* OMP85 proteins contain a common epitope sequence capable of inducing similarly binding antisera. This would be clearly understood by one of skill in the art considering the degree of identity of the SEQ ID NO: 2 and 4 sequences, as well as the virtual identity of the two sequences in the span of amino acids 1-178.

It is not necessary for written description of this invention to define precisely the epitope of OMP85 itself. It is sufficient for written description of this invention that Applicants have described the OMP85 protein or polypeptide that contains an epitope to which the antisera binds and that is capable of inducing the antisera for use in an immunogenic composition. One of skill in the art is aware that the identification of the precise epitope (which is a routine matter given the identification of the protein that contains it) is not necessary in order to identify a protein or polypeptide useful to induce antisera.

The description and teaching at page 20, lines 25-29 coupled with the description and teaching of Example 8 provides the essential written description to convey to the person of skill in the art that antisera to an OMP85 protein with the extremely high degree of similarity to SEQ ID NO: 4 also prevents binding between a *Neisseria* species, the *N. gonorrhoeae* species exemplified, and the known cellular target, an epithelial cell.

The specification thus clearly provides written description for the selection and use of the *Neisseria gonorrhoeae* and *Neisseria meningitidis* OMP85 proteins as useful immunogens, the strong homology of the sequences between the *Neisseria gonorrhoeae* and *Neisseria meningitidis* species (described functionally and by analysis of the two exemplified amino acid sequences SEQ ID NOs: 2 and 4) and the ability of these proteins to induce antisera in a mammal, *e.g.*, a laboratory rabbit model, that can interfere with the ability of the *Neisseria* pathogen to attach to its cellular target. As the prior art at the time of filing of the priority document, was clearly aware that invasion of epithelial cells was critical to infection by *Neisseria* pathogenic species[3], this specification identified the value of these OMP85 proteins, as opposed to the larger outer membrane proteins known in the art for these pathogens.

Applicants incorporate the support explicitly provided in the preceding response, with which the examiner has disagreed. Given the entirety of the specification, the amendments herein which closely track language used in the specification, the supporting portions of the specification identified herein and in the preceding response, and the understanding of the skilled artisan, none of the pending, rejected claims run afoul of the written description requirement. All new and amended claim language is supported by written description in the present continuation application and its priority documents. Therefore, this rejection should be properly withdrawn. Needless to say, there is no new matter disclosed here. There is no attempt or necessity to amend the specification.[4]

In view of the amended language, Applicants respectfully request that the examiner reconsider and withdraw this rejection as against any of the claims now pending.

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[3] See documents cited in the IDS accompanying this paper.

[4] Even if every nuance of the claims is not explicitly described in the specification, the critical issue is the understanding of the skilled artisan. See, *e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

II. 35 USC §102(b) Rejection

Claims 25, 31-36, 38-42, 44-46 50, 52, and 53 are allegedly anticipated by Manning et al, Microb. Pathogen., 25:11-22 (1998), using Richarme et al, Ann. Microbiol. 133A:199204 (1982) to show that every element of the claimed subject matter is disclosed by Manning. The examiner applies this rejection because the examiner asserts that Applicants' pending claims are not entitled to their priority date and are permitted only the date of June 26, 2003, thereby making this document a basis for prior art rejection.

Applicants respectfully request reconsideration and withdrawal of this ground for rejection in view of the above amendments and the following remarks.

Claim 25 and Claim 50, as amended, and new Claim 55 are supported in the parent specification as filed and as discussed above. The claims are supported by written description in the priority applications and the present application as discussed above. The pending specification is a continuation of the prior application filed October 22, 1998 and has the same specification with minor formal and grammatical corrections. As argued above, there is no attempt to introduce new matter into the specification.

Therefore, this rejection cannot stand. Manning is therefore not §102(b) prior art, given the priority date to which this application is entitled. The previously filed *In re Katz* declaration removes Manning from citation as §102(a) prior art and thereby moots this rejection.

III. 35 USC §112, Second Paragraph Rejection

Claims 25 and 39-46 are rejected as allegedly being indefinite for use of "an isolated polypeptide of claim 50".

Applicants express appreciation to the examiner for indicating the ambiguity in the reference in Claim 25 to Claim 50. Therefore, Applicants have amended Claim 25 to replace the language "of Claim 50", removing the inadvertent ambiguity and have defined the polypeptide more clearly. In view of this amendment, Applicants request reconsideration and withdrawal of this rejection

IV. Supplemental Information Disclosure Statement

A supplemental information disclosure statement is provided herewith to present the examiner with the publications recited in the above arguments.

The above amendments and remarks are believed to fully comply with the requirements for patentability. As such, Applicants request that the examiner allow this application to pass to issuance in due course.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account Number 08-3040.

Respectfully submitted,

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